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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,921	02/07/2001	Gennady Merkulov	CL001103	6182

25748 7590 05/13/2003

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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/777,921

Applicant(s)  
Merkulov et al.

Examiner  
John Ulm

Art Unit  
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 19, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 4, 8, 9, and 24-29 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 8, 9, and 24-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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1) Claims 4, 8, 9 and 24 to 29 are pending in the instant application. Claims 24 and 28 have been amended as requested by Applicant in Paper Number 13, filed 19 February of 2003.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) The corrected or substitute drawings were received on 19 February of 2003. These drawings are approved.

5) Claims 4, 8, 9 and 24 to 29 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 5 of Paper Number 12. As stated therein, the instant application has provided a description of an isolated DNA encoding a putative transporter protein and the protein encoded thereby but it does not disclose a specific biological role for this protein or its significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

Applicant has traversed this rejection on the premise that the disclosure of an isolated nucleic acid encoding a protein which is potentially a calcium binding transporter is, alone, sufficient to establish a utility for a specific protein and, therefore, the claimed nucleic acid. Applicant asserts that a protein of the instant invention belongs to a family of proteins of which some members are the targets of therapeutic agents and, as such, that protein has valuable

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commercial utilities in the drug discovery process by providing previously unidentified members of an important pharmacological target class. This argument is not persuasive because each clinical agent which has been developed by measuring its interaction with a specific protein such as a receptor proteins, a transporter proteins or a specific enzyme was evaluated against a target protein whose native physiological functions were known, such as the calcium channels, the adrenergic receptors, the dopamine receptors, the serotonin receptors, the serotonin transporters and the bacterial enzymes involved in protein and cell wall synthesis. There are also numerous proteins such as odorant receptors and calcium sensing receptors which do not appear to mediate any clinically significant process. More importantly, an artisan knew, before they employed a specific target protein to identify clinically useful compounds, which physiological process or processes they wished to manipulate and that the protein employed in their assay had an influence on that process. Even if one identifies an agonist or antagonist for a transporter protein encoded by the instant invention, this information is of no substantial practical value since one can not predict what clinical effect the administration of that agonist or antagonist to an individual would have by simply observing that the compound in question has the ability to effect the activity of the putative transporter protein encoded by the claimed polynucleotide. Because instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect, employing that protein to identify agonists or antagonists thereto is an activity which is of no immediate and substantial practical value.

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Applicant urges that the protein encoded by the claimed polynucleotide “is very similar to the calcium-binding transporters” and extrapolates from this observation to conclude that a protein of the instant invention is a mitochondrial solute carrier protein “useful for diagnosing and/or treating mitochondrial-associated diseases/disorders”. A search of the amino acid sequence presented in SEQ ID NO:2 of the instant specification shows that it is 95.6% identical to the amino acid sequence of the rabbit “peroxisomal  $\text{Ca}^{2+}$ -dependant member of the mitochondrial carrier superfamily” which was described by Weber et al. (P.N.A.S. 94:8509-8514, Aug. 1997) and, therefore, one of ordinary skill in the art would conclude that a protein of the instant invention is the human homolog of the carrier protein of Weber et al. The third full paragraph on page 8513 of Weber et al. states that “[t]he mainly hydrophobic C-terminal half of our solute carrier is related to Graves disease carrier, for which no function has yet been assigned”. After considering all of the evidence disclosed therein, this publication concludes by stating that “[o]ne could speculate that the coordinated action of” the peroxisome-proliferator activated nuclear receptor and the peroxisomal  $\text{Ca}^{2+}$ -dependant solute carrier of the instant invention “to induce peroxisome proliferation via a  $\text{Ca}^{2+}$  signal and the onset of transcription prevents the accumulation of long-chain fatty acids in colonocytes and thus prevents colon carcinogenesis”. Absent this concluding statement, neither the instant specification nor the art of record identified a specific disease or disorder, mitochondrial-associated or otherwise, which has been reasonably shown to be associated with a protein of the instant invention. Further, the concluding statement of Weber et al. was expressly identified therein as speculative. It is clear

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that substantial additional experimentation would be required to establish a role for a protein of the instant invention in preventing colon carcinogenesis and the court allows for no additional experimentation if it is required to identify a specific and substantial utility for the claimed invention. Such need for additional experimentation was precluded by the court when it said that “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion”, *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), as cited in the original rejection.

Applicant has traversed this rejection on the premise that the claimed polynucleotide can be employed as a probe, primer or chemical intermediate and the employment of that polynucleotide in this capacity is a credible, specific and substantial utility. The employment of a nucleic acid of the instant invention as a probe, primer or chemical intermediate is not a substantial or specific utility. All human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any nucleic acid encoding a protein which is expressed in a tissue specific manner can be employed as a probe to detect the tissue in which it is expressed in a sample. Alternately, a nucleic acid encoding a human protein which is expressed ubiquitously can be employed as a probe to detect the presence of any human tissue in a sample. Further, any cDNA can be employed as a probe, primer, or in a process of producing the protein

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encoded thereby. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

One could just as readily argue that any purified compound having a known structure could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromatography (HPLC) and gas chromatography. None of these processes could be practiced without either calibration standards having known molecular structures or, at least, a range of molecular weight markers having known molecular weights. One could further extrapolate upon this premise by asserting that any item having a fixed measurable parameter can be employed to calibrate any machine or process which measures that parameter. For example, any item having a constant mass within an acceptable range can be employed to calibrate a produce scale in a grocery store. The calibration of produce scales is certainly an important function since most states require produce scales to be calibrated and certified. Therefore, to accept Applicant's arguments that any nucleic acid encoding any protein of human origin is useful as a marker would be comparable to conceding that any object of fixed mass has *prima facie* utility as a weight standard, irrespective of any other properties possessed by that object. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound which was the subject of that

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decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that time. Further, because that compound was a hydrocarbon it certainly could have been employed in the well known process of combustion for purposes of lighting and/or the generation of heat. The generation of heat by combustion of hydrocarbons certainly was and remains an important process. Irrespective of such obvious utilities, the court still held that the compound produced by the process at issue in *Brenner v. Manson* did not have a specific and substantial utility.

To grant Applicant a patent encompassing an isolated polynucleotide encoding a naturally occurring human "anion transporter" protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" (*Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed polynucleotide based solely upon an assertion that it can be employed as a probe, primer or chemical intermediate is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in *Brenner v. Manson* on the premise that the steroid produced thereby was useful as an analytical standard or as a combustible fuel source.

The rejection is maintained because Applicant has failed to identify a specific and substantial utility for all calcium-dependant transporter proteins or for the particular protein

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encoded by the claimed nucleic acid. To employ a protein of the instant invention in the identification of compounds which act upon that protein without knowing the physiological relevance of that action is to employ the protein encoded by the claimed nucleic acid as the object of that further research which must be completed before the claimed nucleic acid is useful in a currently available form.

6) Claims 4, 8, 9 and 24 to 29 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Applicant's arguments filed 19 February of 2003 have been fully considered but they are not persuasive for those reasons given above.

8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

a shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800